



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

93839d

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

February 26, 2003

WARNING LETTER
CHI-9-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Adam Lustbader, President
Concept Laboratories, Inc.
1400 W. Wabansia Avenue
Chicago, IL 60622

Dear Mr. Lustbader:

An inspection of your firm, which manufactures OTC topical pharmaceutical products and cosmetics, was conducted from January 7 through 22, 2003, by Investigator Russell K. Riley. Investigator Riley found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act) as they pertain to drug products manufactured in your plant. Our review of the inspection determined that the pharmaceutical products manufactured by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act because they were not manufactured in accordance with current Good Manufacturing Practice Regulations (cGMP) under Title 21, Code of Federal Regulations (CFR), Parts 210 and 211.

The deviations from the cGMP's found during the inspection, and reported on the Form FDA 483, Inspectional Observations, that was presented to you at the conclusion of the inspection, include the following:

1. Failure to follow written procedures for the cleaning and maintenance of equipment, including utensils, that are used in the manufacture, processing, packing or holding of a drug product as required by 21 CFR 211.67(b). For example, no validation has been performed on the equipment cleaning and sanitizing procedure, Test Method CL-1000. This procedure is used for the cleaning of all tanks, totes and filling equipment after the manufacture of all products, including industrial cleaners, cosmetics and OTC pharmaceutical products.
2. Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, including the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance as required by

21 CFR 211.67(b)(3). For example, Test Method CL-1000 does not specify the type of germicidal detergent or sanitizer to be used in cleaning the kettles and tanks. This procedure also does not discuss the spraying of [REDACTED] onto cleaned equipment, which was described to Investigator Riley as part of the equipment cleaning process.

3. Drug products failing to meet established specifications are not rejected as required by 21 CFR 211.165(f). For example, Skin Zinc Spray, batch [REDACTED] was released despite the fact that this product failed to meet the specification for the assay of the active ingredient, Zinc Pyrithione, in two out of three tests. Another example is the pH release test for Glucosamine Pain Relief Gel, batch [REDACTED]. The pH was 6.20. The specification for this test is 6.5 – 7.5. This lot was also released.
4. Master production and control records are deficient in that they do not include complete manufacturing instructions, sampling procedures, and specifications are required by 21 CFR 211.186. For example: The master record for Skin Zinc Spray indicates that a test for viscosity is required, but the master record does not indicate a specification range. Also, the master record fails to provide sampling instructions that discuss how a sample is to be collected, the size of the sample and the location where the sample is to be collected.
5. Batch production and control records are deficient in that they do not include the identity of major equipment used as required by 21 CFR 211.188(b)(2).
6. Drug product production and control records are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Also, written records of investigations into the failure of a batch or any of its components to meet any of its specifications are not made as required by 21 CFR 211.192.

The above identification of violations and the Form FDA 483, Inspectional Observations, issued and discussed with you at the conclusion of the inspection, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the cGMP regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

Please submit in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violation.

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You should take prompt action to correct these deviations. Failure to correct the deviations noted may result in regulatory action without further notice. These include seizure and/or injunction.

Your response should be sent to the attention of George F. Bailey, Compliance Officer at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director